

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

THIS DOCUMENT RELATES TO:

Track Seven

**MDL No. 2804
Case No. 17-md-2804
Judge Dan Aaron Polster**

**KROGER DEFENDANTS' *DAUBERT* MOTION
TO EXCLUDE PORTIONS OF ANNA LEMBKE'S, DAVID COURTWRIGHT'S, AND
JAMES RAFALSKI'S OPINIONS THAT VIOLATE PRIOR COURT ORDERS**

Defendants The Kroger Co., Kroger Limited Partnership I, and Kroger Limited Partnership II (hereafter collectively referred to as "Kroger"), seek to exclude portions of Dr. Anna Lembke's, Dr. David Courtwright's, and James Rafalski's expert reports and proffered testimony to the extent they violate Orders previously entered by the Court in prior MDL tracks.¹

The Court, in its *Nunc Pro Tunc* Evidentiary Order in Track 3, noted that all prior evidentiary orders from the various MDL Tracks will "normally apply to all future cases in the MDL..." including "remanded cases tried by transferor courts." Dkt. 3058 at 1. Therefore, the Court should apply its prior rulings to these Track 7 expert reports and, for the foregoing reasons, exclude portions of Dr. Lembke's and Dr. Courtwright's Expert Reports in which they (1) opine on a cause-and-effect relationship between Kroger's allegedly false and misleading marketing efforts and an actual increase in the supply of prescription opioids or harms allegedly caused by those opioids; or (2) opine that Kroger failed to provide its pharmacists with sufficient time,

¹ This Motion does not encompass all of Kroger's objections to Plaintiff's expert reports – only those grounded in *Daubert*.

resources, or incentives to investigate red flags. Additionally, the Court should exclude portions of James Rafalski's Track 7 Expert Report that contain legal conclusions or interpretations of law.

A. Dr. Anna Lembke

Significant portions of Dr. Lembke's Track 7 Expert Report explicitly violate the Court's prior Track Three Order. *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2021 WL 4243084, at *1 (N.D. Ohio Sept. 17, 2021) (See generally Dkt. 3953). The Court previously granted the Track Three Pharmacy Defendants' Motion to Exclude Testimony of Anna Lembke to the extent she testified regarding "the cause-and-effect relationship between false and misleading promotion, increased opioid prescribing, and increased harms," and stated that she could not testify regarding pharmacy policy or procedure that are outside the scope of her expertise as a physician and addiction expert. *Id.* at 4, 7, and 13. A specific example of what the Court found to be not within Dr. Lembke's scope of expertise was testimony that Pharmacy Defendants "failed to provide pharmacists with sufficient time, resources, or incentives to investigate red flags." *Id.* at 13.

1. Marketing Causation

Several opinions in Dr. Lembke's Track Seven Expert Report violate the Courts' Track One and Track Three Orders against testimony concerning marketing causation and should therefore be excluded. *See id. See also In re Opiate*, 2019 WL 4054054998 (N.D. Ohio Aug. 28, 2019). In Track One, the Court found that Dr. Lembke was not qualified to offer opinion and testimony "regarding a causal connection with respect to pharmaceutical marketing, *i.e.*, that Defendants' marketing efforts resulted in increased sales and/or increased supply of prescription opioids." *In re Opiate*, 2019 WL 4054054998 at *6. In Track Three, the Court affirmed this ruling, finding that the plaintiff's new evidence that Dr. Lembke had allegedly expanded her field of

expertise regarding pharmaceutical marketing was insufficient to qualify her to opine regarding a causal connection between the Pharmacy Defendants' marketing of opioids and an increase in the supply of prescription opioids. Dkt. 3953 at 6-7.

Beginning on page 27 of Dr. Lembke's Track Seven Report, she offers the opinion, titled under subheading 4 ("Opinion #4"), that "The Pharmaceutical Opioid Industry"^{2,3} contributed substantially to the paradigm shift in opioid prescribing through misleading messaging about the efficacy of prescription opioids." She further concludes that "Starting in the late 1990s, due to the Pharmaceutical Opioid Industry's aggressive and misleading promotion, opioids were prescribed in abundance...". Lembke Track Seven Rpt., attached as Exhibit 1, at 27. She goes into extensive detail in her report regarding the various marketing methods the Pharmaceutical Opioid Industry used to allegedly mislead the public into believing prescription opioids were safe and effective to treat chronic pain addiction and concludes that "[t]hese actions directly contributed to the opioid epidemic we face today." *Id.* at 28.

Dr. Lembke's Opinion #4 spans from pages 27 through 91 of her Expert Report and contains numerous other marketing causation conclusions, which this Court in Tracks One and Three specifically excluded. For instance, she argues that the "Pharmaceutical Opioid Industry retained an aggressive sales force incentivized to target doctor's offices and pharmacies to increase sales, thereby increasing the number of people exposed to opioids." *Id.* at 29. She also argues that the evidence she presented regarding several of the Manufacturer Defendants "makes it clear that

² Dr. Lembke notes that, when used in her report, the term "Pharmaceutical Opioid Industry" includes "the defendants in this case" including pharmacies such as Kroger. Lembke Rpt. at 9 n.24.

³ Kroger disputes and does not condone Dr. Lembke lumping opioid manufacturers, distributors, and pharmacies into one overly broad category which she refers to as the "Pharmaceutical Opioid Industry" or "The Industry." Therefore, any reference to the "Pharmaceutical Industry" or "The Industry" in this motion is solely for the purpose of summarizing portions of Dr. Lembke's Expert Report and does not in any way represent agreement with her opinions.

promotion of opioids to prescribers and their staff is a highly effective strategy for increasing opioid sales.” *Id.* at 51.

Additionally, the Court should not be persuaded to alter its prior orders in Tracks One and Three about Dr. Lembke’s qualifications based on her claim that she has “substantial experience in the study and teaching on the marketing of opioids, the impacts of such marketing on prescribing habits of physicians, and the effects of market-driven prescribing as a cause of the ongoing [opioid] epidemic.” *Id.* at 7. In fact, Dr. Lembke’s Track 7 Expert Report contains an identical section concerning her alleged expertise in the alleged cause-and-effect relationship between prescription opioid marketing and an increase in the supply or sale of opioids. *See id. See also* Lembke Track 3 Rpt. (Dkt. 4218-8 at 7). This Court should, therefore, follow its prior ruling in Track 3 and find that Dr. Lembke is still not qualified to testify “regarding a causal connection between the Pharmacy Defendants’ marketing of opioids and an increase in the supply of prescription opioids.” Dkt. 3953 at 6.

Accordingly, the Court should exclude all opinions or conclusions in Dr. Lembke’s Opinion #4, in its entirety, because the majority of the evidence she cites regarding the specific Defendants is offered to support her central conclusion that “due to the Pharmaceutical Opioid Industry’s aggressive and misleading promotion, opioids were prescribed in abundance” *Id.* In the alternative, the Court should exclude all of Dr. Lembke’s statements in Opinion #4 which draw a causal connection between the Defendants’ marketing and an increase in the sale or supply of prescription opioids because she is still not qualified to make those statements. The Court should also exclude all opinions and conclusions in her Expert Report that “Kroger’s “marketing efforts resulted in increased sales and/or increased supply of prescription opioids.” *In re Opiate*, 2019 WL 4054054998 at *6.

2. Pharmacy Practices and Policies

In Track Three, the Court found that Dr. Lembke's expertise as "a medical expert in psychiatry, addiction and pain" does not allow her to opine on "any and every Pharmacy policy or procedure." Dkt. 3953 at 12 and 13. That court specifically found that nothing in Dr. Lembke's background provided her a basis upon which to conclude that Defendant Pharmacies "*fail[ed] to provide pharmacists with sufficient time, resources, or incentives to investigate red flags.*" *Id.* at 13 (emphasis in original) (citing Lembke Track Three Rpt. at 8). However, in her Track Seven Expert Report, Dr. Lembke parrots this exact opinion⁴ ("Opinion #6") and cites virtually no evidence⁵ of how the Pharmacy Defendants, or Kroger specifically, allegedly failed to provide their pharmacists with the resources or incentives supposedly necessary to investigate red flags. *See* Lembke Track Seven Rpt. at 100. The only direct mention of Kroger in Opinion #6 is the offhand comment that "Kroger pharmacy bonuses were based in part on pharmacist's direct detailing to individual local physicians and doctor's offices." *Id.* at 101.

Dr. Lembke also claims that "Pharmacy Defendants failed to adequately respond to 'red flags' for misuse and diversion or *support individual pharmacists in these efforts.*" Lembke Track Seven Rpt. at 142 (emphasis added). Thereafter, she mentions only her personal experience with pharmacists with whom she claims a frequent topic of conversation was "the need for diligent investigation of red flags" and a study from the National Association of Boards of Pharmacy, which she argues shows that "Pharmacy policies and procedures may purport to impose

⁴ In her Track 7 Expert Report, Dr. Lembke specifically opines that "[Pharmacies] ignored 'red flags' for misuse and diversion...and *failed to provide pharmacists with sufficient time, resources, or incentives to investigate red flags*". Lembke Track 7 Rpt. at 100 (emphasis added).

⁵ Dr. Lembke references only anecdotal evidence from 2020 and 2021 follow-up surveys from the State of Ohio Board of Pharmacist Workload Survey, where a few respondents happened to mention Kroger. *See* Lembke Track 7 Rpt., Appendix III at 388 and 398-400.

requirements of sound professional judgment . . . but [] offer little protection when pharmacists are overwhelmed by the need to meet . . . performance metrics.”

Dr. Lembke’s assertion that the Pharmacy Defendants, including Kroger, failed to support individual pharmacy efforts to prevent prescription opioid misuse and diversion is simply a restatement of her broader argument that the Defendant Pharmacies failed to provide pharmacists with sufficient time, resources, etc., to investigate red flags. Therefore, the opinion that “Pharmacy Defendants failed to adequately respond to ‘red flags’ for misuse and diversion or support individual pharmacists in these efforts” and any related opinions should be excluded for the same reasons.

Further, Dr. Lembke does not list any additional qualifications following the Court’s Track Three Order excluding her from opining about whether Defendants failed to provide adequate time, resources, and support to investigate red flags. She claims that since the time of her previous report in this litigation, she has “conducted further research concerning the role of pharmacies in the opioid epidemic” and has also reviewed documents provided by counsel on that subject. *Id.* at 7-8. However, this statement merely parrots her qualifications listed in her Track Three Expert Report,⁶ which the Court found did not make her qualified to offer an opinion regarding pharmacists and the investigation of red flags. Dkt. 4219-8 at 6; Dkt. 3953 at 13. Accordingly, this Court should find, as it did in Track Three, that Dr. Lembke is still not qualified to offer this opinion.

The Court should exclude Dr. Lembke’s opinion that the Defendants “failed to provide pharmacies with sufficient time, resources, or incentives to investigate red flags” and that

⁶ In her Track 3 Expert Report, Dr. Lembke states that “Since the time of [her] previous report in this litigation, [she has] conducted further research concerning the role of pharmacies in the opioid epidemic, and [she has] also reviewed documents provided by counsel on that subject.” Dkt. 4219-8 at 6.

“Pharmacy Defendants failed to adequately respond to ‘red flags’ for misuse and diversion or support individual pharmacists with this effort” because the Court has already excluded the same, finding such opinions outside the scope of her expertise and misleading and factually unsupported.

B. David Courtwright

David Courtwright, like Dr. Lembke, improperly proffers an opinion concerning marketing causation. From nothing but a historical review of literature on the opioid epidemic coupled with sparse information implicating Kroger, he opines as follows:

National pharmacies [including Kroger] assisted manufacturers by promoting branded opioid products and by arranging for their pharmacists to receive manufacturer-sponsored pro-opioid educational materials and to participate in manufacturer-sponsored continuing education programs. . . . [and] compounded the diversion problem by continuing to fill suspicious opioid prescriptions, despite detailed warnings from law enforcement and from their own employees. . . . whence large quantities of painkillers were diverted into the illicit interstate traffic.

Courtwright Track Seven Rpt., attached as Exhibit 2, at 10. Indeed, the conclusion of his 395 page report, in pertinent part, is as follows:

[N]ational pharmacies all played multiple roles in that campaign [“to subvert narcotic conservatism and the strict regulatory regime with which it was associated”]. The common, intended effect of their efforts was to substantially increase exposure to prescription opioids, despite their known addictive and toxic properties. The result of that exposure was that Ohioans and other Americans endured a second prolonged epidemic of medicinal opioid addiction

...

Id. at 395.

Dr. Courtwright, a historian,⁷ is no more qualified than Dr. Lembke to offer an opinion “regarding a causal connection with respect to pharmaceutical marketing, *i.e.*, that Defendants’

⁷ Dr. Courtwright is Presidential Professor Emeritus in the Department of History of the University of North Florida. Courtwright Track Seven Rpt. at 3.

marketing efforts resulted in increased sales and/or increased supply of prescription opioids."

See In re Opiate, 2019 WL 4054054998 at *6; Dkt. 3953 at 6-7. As such, any such conclusory opinions should be excluded.

C. James Rafalski

Portions of James Rafalski's Track 7 Expert Report contain legal conclusions and interpretations of law which explicitly violate the Courts' rulings in Track One and Track Three. In Track 1, the Court found that James Rafalski has "no legal training and is not an expert in the law" and therefore "to the extent Rafalski expresses opinions as to what the law requires . . . his opinions are not admissible." *In re Opiate*, 2019 WL 3934490, at *3-5 (N.D. Ohio Aug. 20, 2019) (Dkt. 2494 at 8). This Court upheld its ruling in Track 3, finding that "the Court will impose well-established legal principles generally prohibiting experts from opining as to what the law requires." *In re Opiate*, 2021 WL 4060359 at *2 (N.D. Ohio Sept. 7, 2021) (Dkt. 3929 at 7) (citing Dkt. 2494 at 7-8 and *Berry v. City of Detroit*, 25 F.3d 1342, 1353-54 (6th Cir. 1994)).

Rafalski's opinion under the "L. DEA CHEMICAL HANDLER'S MANUAL" subheading ("Section L") contains an interpretation of federal law regarding what is required for the Suspicious Order Monitoring System ("SOMS") for DEA registrants under 21 CFR 1301.74(b) and should therefore be excluded. *See* Rafalski Track Seven Rpt., attached as Exhibit 3, at 37. Rafalski attempts to draw a parallel between the DEA's Chemical Handlers Manual and guidelines related to "Suspicious Orders of Listed Chemicals," which is defined by 21 USC § 830(b)(1)(A) as "orders of 'extraordinary' size," and the requirement under 21 CFR 1301.74(b) that DEA registrants must "design and operate a system to disclose to the registrant suspicious orders of controlled substances." *Id.* He concludes, by conflating the requirements of the two statutes, that a threshold of "extraordinary size" for Listed Chemicals in 21 USC § 830 would "[fail] to detect orders of

'unusual size' and is thus not compliant with 21 CFR 1301.74(b)." *Id.* (quoting 21 USC § 830(b)(1)(A)).

Here, Rafalski is clearly comparing the definitions within the two statutes and rendering a legal interpretation of what an inadequate SOMS system would be under 21 CFR 1301.74(b). Rafalski does not assert any additional qualifications, e.g., a law school degree or license to practice law, in his Track Seven Expert Report that would now allow him to "opine as to what the law requires." Dkt. 2494 at 8. Therefore, the Court should exclude, in the entirety, his opinions under Section L and throughout his report to the extent they contain legal conclusions or interpretations of law.

Dated: February 8, 2023

Respectfully submitted,

**The Kroger Co., Kroger Limited
Partnership I, Kroger Limited
Partnership II,**

By counsel,

s/Ronda L. Harvey

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CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that on February 8, 2023, the foregoing document was filed with the Clerk of Court using the CM/ECF system and I have served all counsel of record via email.

Dated: February 8, 2023

s/Ronda L. Harvey
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